

## § 520.2362

tetracycline hydrochloride, 60 milligrams of novobiocin, and 1.5 milligrams of prednisolone or 180 milligrams of tetracycline hydrochloride, 180 milligrams of novobiocin, and 4.5 milligrams of prednisolone.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 10 milligrams of each antibiotic and 0.25 milligram of prednisolone per pound of body weight (one single-strength tablet for each 6 pounds or one triple-strength tablet for each 18 pounds) every 12 hours for 48 hours. Treatment is to be continued with novobiocin and tetracycline alone at the same dose schedule for an additional 3 days or longer as needed.

(2) *Indications for use*. Treatment of acute and chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli*, when it is necessary to initially reduce the severity of associated clinical signs.

(3) *Limitations*. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment should be conducted. Administer for 48 hours only. Continue treatment if needed with tetracycline/novobiocin alone. The product is contraindicated in animals with tuberculosis, hyperadrenocorticalism, or peptic ulcers. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

## § 520.2362 Thienium closylate tablets.

(a) *Chemical name*. (N,N-Dimethyl-N-2-phenoxyethyl-N-2'-thenylammonium)-p-chlorobenzene-sulfonate.

(b) *Specifications*. Thienium closylate tablets contain thienium closylate

## 21 CFR Ch. I (4–1–12 Edition)

equivalent to 500 milligrams thienium as base in each tablet.

(c) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) The tablets are administered orally to dogs as a single day treatment of canine ancylostomiasis by the removal from the intestines of the adult forms of the species *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms). Dogs weighing 10 pounds and over are administered 1 tablet as a single dose. Dogs weighing 5 to 10 pounds are administered one-half tablet twice during a single day. All dosages are given for 1 day only. The treatment should be repeated after 2 or 3 weeks.

(2) Suckling puppies or recently weaned puppies weighing less than 5 pounds should not be treated with the drug. Animals that are severely infected, exhibiting evidence of intestinal hemorrhage, debilitation, and anemia, should be given supportive treatment.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 53477, Dec. 7, 1976; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

## § 520.2380 Thiabendazole oral dosage forms.

### § 520.2380a Thiabendazole top dressing and mineral protein block.

(a) *Chemical name*. 2-(4-Thiazolyl)-benzimidazole.

(b) *Specifications*. Conforms to N.F. XII.

(c) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 051311 for use as in paragraph (e)(1)(i) of this section.

(2) No. 050604 for use as in paragraph (e)(1)(ii) of this section.

(3) No. 012286 for use as in paragraph (e)(2) of this section.

(d) *Related tolerances*. See § 556.730 of this chapter.

(e) *Conditions of use*. It is used as follows:

(1) *Horses*—(i) *Route of administration*. In feed, as a top dressing.

(a) *Amount*. 2 grams per 100 pounds of body weight.